

Applicant: Bonutti et al.  
Application No.: 10/760,598  
Examiner: M. Brown

### REMARKS

Claims 1-23 are pending in the application and are presented for the Examiner's review and consideration. Claims 1, 15, and 23 have been amended. Applicants believe that the claim amendments and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicants respectfully submit that they do not limit the range of any permissible equivalents.

#### 35 U.S.C. § 103(a)

Claims 1-3, 6-9, 12-18, and 20-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,407,420 to Bastyr et al. ("Bastyr") in view of U.S. Patent No. 5,417,643 to Taylor ("Taylor"). For the reasons set forth below, Applicants respectfully submit that the rejected claims are patentable over Bastyr in view of Taylor.

As discussed in the Response to the initial Office Action, Bastyr discloses an orthopedic shoulder brace worn on the body of a patient and for stabilizing and immobilizing a shoulder of a patient. The brace is affixed to the torso, upper arm, and forearm of the patient with cuffs. A plurality of joint assemblies interconnect the cuffs, allowing the brace to be adjusted to fix the shoulder in virtually any position. The joints assemblies include a shoulder abduction joint, a shoulder flexion joint, a shoulder rotation joint, and an elbow flexion joint. The elbow flexion joint allows the forearm to adjustably positioned with respect to the upper arm in flexion. The shoulder rotation joint is integral with an upper arm linkage, such that the axis of rotation of the joint is collinear with its adjacent support member. The axes of rotation of the remaining joints are perpendicular to the respective adjacent support members.

For the reasons set forth in the prior Response, Applicants maintain that Bastyr is not analogous prior art. Applicants do not dispute that the terms "brace" and "orthosis" are both used in the surgical art. However, they are not interchangeable, particularly in this case in which the brace of Bastyr is used for stabilizing and immobilizing (fixation) of a shoulder of a patient, and

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the orthosis of the present invention is used to include the range of motion of a shoulder.

In the Final Office Action, it is stated that "no patentable weight can be given to whether Bastyr is used to hold the arm in a specific position." Applicants agree and submit that this is not the appropriate inquiry. The correct inquiry would be whether one of ordinary skill in the art would consider Bastyr, a device to immobilize a joint, as being relevant to the patentability to Applicants' invention, a device to increase the range of motion.

This inquiry also relates to the proposed combination of Bastyr and Taylor. The secondary reference, Taylor, discloses a continuous passive motion device, in which the user is seated, for use in the treatment of infirmities of the arms and shoulders. The device includes a pair of interconnected drive units, an elevation drive unit and a rotational drive unit connected to a chair. The elevation drive unit enables the patient's arm to be elevated from a position proximal to the torso of the patient to a fully extended over head position. The rotation drive unit rotates the patient's arm through an arc which traverses the patient's scapular plane. The elevation drive unit and the rotation drive unit work in concert to continuously move the patient's arm through the therapeutic range of motion.

Applicants note that there is no motivation to combine the references, either in the references themselves or to one of ordinary skill in the art. As noted above, Bastyr is directed towards a wearable brace for stabilizing and immobilizing a shoulder whereas Taylor is directed towards continuous passive motion exercise device that a user sits in and treats an arm. As such, Bastyr and Taylor are directed towards opposing forms of treatment, namely, immobilization verses continuous passive motion. Accordingly, there is no explicit or inherent disclosure to modify the references or to combine teachings of the references.

In fact, the inclusion of the Taylor drive unit in the Bastyr device would defeat the purpose of Bastyr, namely, an immobilization of the shoulder. As set forth in the prior Response, the Bastyr joints and the Taylor drive units perform different functions and exhibit different non-interchangeable movements in performing these functions. Finally, the Bastyr device is a mobile device to be continuously worn by the patient. The Taylor device is a bulky exercise device, in

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which the patient sits. The device is not a mobile device intended to be continuously worn by the patient. As such, there is no indication that the Taylor drive units can be successfully incorporated into the Bastyr device.

Even if Bastyr and Taylor were combined as suggested, the references still do not teach or suggest all the claim elements. As previously described, Bastyr rotates the upper arm about an axis spaced a distance away from the humerus bone of the upper arm. Even if Taylor's drive mechanisms are used with Bastyr's device, the axis of rotation of the upper arm is still located a distance from the humerus bone. In contrast, Applicants rotate the upper arm about the central longitudinal axis of the humerus bone.

Contrary to the Examiner's assertions, Applicants are not trying to claim the function of locating different portions of the body. Rather, Applicants respectfully submit that the structural elements recited in the claims differentiate the claimed invention from the cited prior art. Furthermore, it is the claimed structural elements and the arrangement thereof that are properly recited and given patentable weight. For example, independent claim 15 recites that the drive member is connected to the lower arm section to move the lower arm section relative to the upper arm section such that the lower arm portion is rotated about the central longitudinal axis of the humerus bone while the lower arm portion remains substantially orthogonal to the upper arm portion. The other two independent claims contain analogous recitations. It is the structure of the drive member and the relationship to the upper and lower arm sections that allow the claimed device to rotate the lower arm section while remaining substantially perpendicular to the upper arm section.

In light of the foregoing, independent claims 1, 15, and 23 are respectfully submitted to be patentable over Bastyr in view of Taylor. As claims 2, 3, 6-9 and 12-14 depend from claim 1 and claims 16-18 and 20-22 depend from claim 15, and necessarily include all the elements of their base claims, Applicants respectfully submit that these dependent claims are also patentable at least for the same reasons.

Claims 4, 5, 10, 11, and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable

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over Bastyr in view of Taylor in further view of U.S. Patent No. 5,538,499 to Schween et al. ("Schween"). The inclusion of Schween fails to overcome the deficiencies in Bastyr and Taylor. As claims 4, 5, 10 and 11 depend from claim 1 and claim 19 depends from claim 15, and necessarily include all the elements of their base claims, Applicants respectfully submit that these dependent claims are also patentable at least for the same reasons.

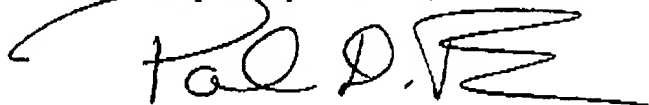
In light of the foregoing, claims 4, 5, 10, 11, and 19 are respectfully submitted to be patentable over Bastyr in view of Taylor in further view Schween.

#### Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$395 is believed to be due for a Request for Continued Examination. A fee of \$225 is also believed to be due for a two month extension of time. A PTO-2038 Credit Card Payment Form for both of these fees is submitted herewith. Please charge any additional fees (or credit any overpayment of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A04-006-3).

Respectfully submitted,



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